Remarks

Claims 37-85 are pending in the subject application. By this Amendment, claims 37, 48, 66, 67, 78, and 82 have been amended. Support for these amendments can be found throughout the subject specification. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with or acquiescence to, the rejections of record. Favorable consideration of claims 37-85, in view of the amendments and remarks set forth herein, is earnestly solicited.

As an initial matter, the applicants wish to thank Examiner Lewis for the courtesy extended to the undersigned during the personal Examiner Interview conducted on March 28, 2005. This response and the amendments set forth herein are submitted in accordance with the substance of that interview and constitutes a summary thereof. Specifically, the applicants wish to expedite prosecution by focusing the claims on the applicants' unique and advantageous method for providing automated, appropriate ventilation using only the input of patient body length. The applicants respectfully submit that the claims now presented define an invention that was not previously known in the art. Accordingly, applicants respectfully request favorable consideration of the claims now presented.

In considering the patentability of the subject invention, it is very important to appreciate that the claimed invention is directed to methods for providing ventilation, which include calculating, in a ventilator control device, either a ventilation parameter, a ventilatory limit, or a ventilation alarm setting using solely patient body length that is input into the ventilator control device. These methods are particularly advantageous in that they are simple to implement and enable accurate ventilatory operation. The cited art, as discussed below, fails to teach or even suggest the claimed methods. Under these circumstances, the subject invention cannot reasonably be said to be obvious.

Claims 37-85 have been rejected under 35 U.S.C. §103(a) as obvious over Kanesaka (U.S. Patent No. 5,042,470), in view of Heinonen (U.S. Patent No. 5,645,531) and Haluszka *et al* ("Whole Body Plethysmography"). The applicants respectfully traverse this grounds for rejection because the cited references, alone or in combination, do not disclose or suggest the claimed methods.

To establish *prima facie* obviousness, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). A careful review of the Kanesaka reference reveals: a ventilator that does not include a means for inputting patient body length into a control device and a control device that does not calculate ventilatory parameters based on patient body length. Moreover, Kanesaka fails to describe a method for automatically calculating appropriate ventilation (*i.e.*, ventilation parameter) based on patient body length, which is input into a ventilator control device.

The Kanesaka reference merely teaches conventional techniques for setting up a ventilator. As is clearly stated in Kanesaka, "the main section (1) and auxiliary section (5) [for supplying gas to a patient, see col. 2, lines 52-64] *must be manually set.*" (emphasis added). Kanesaka further elaborates that manual selection of the ventilator settings (such as ventilating pressure, tidal volume, Inspire/Expire ratio, and frequency of breath) is based upon clinician assessment of patient characteristics such as weight, height, sex, and other clinical conditions (see col. 4, lines 16-24). The reference does not teach or suggest inputting patient body length into a ventilator let alone solely using patient body length to establish an operating parameter of the ventilator. In truth, the Kanesaka reference teaches that a clinician, and not a ventilator, must use several clinical conditions (such as patient weight, height sex, *etc.*) to identify appropriate ventilatory settings. To suggest that the ventilator is identifying an operating parameter based on input patient height data, is to misread the Kanesaka reference or, perhaps, to read too much into Kanesaka's description.

As noted above, there is no description by Kanesaka of inputting data regarding patient height into a ventilator control device so that the control device can calculate either ventilation parameters, ventilatory limits, or ventilation alarm settings. Nor does Kanesaka describe providing ventilation to a patient using only patient body length. In order to establish a case of *prima facie* obviousness, it is incumbent upon the Patent Office to determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole. See *In re Jones*, 958 F.2d 347, 351 (Fed. Cir. 1992) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed...modifications needed to arrive at the claimed invention."). The Office Action provides no indication as to why the skilled artisan would have been motivated to select the Kanesaka reference, much less modify its teachings, to

arrive at the subject method for providing appropriate ventilation based solely upon a patient's body length.

Further, the Heinonen reference does not cure the shortcomings of the Kanesaka reference. The Heinonen merely teaches that anesthesia flow must be monitored to enable delivery of proper anesthesia concentration to a patient. Heinonen does not describe any method for providing ventilation to a patient wherein data representing patient height is input into a ventilator control device that calculates ventilation parameters, ventilatory limits, or ventilation alarm settings based solely upon patient body length.

The Office Action at the bottom of page 2, states that the Heinonen device "render[s]...respiratory ventilation control values (col. 8 lines 19-40) based upon data input." Upon closer scrutiny, Heinonen only describes providing data regarding the flow of anesthetic elements to a ventilator. For instance, the description at col. 8, lines 19-40 of the Heinonen reference is directed to measuring elements 15, 16, 29, 33, 39, and 40, which monitor the pressure of anesthetic flow (or in the case of measuring element 40, anesthetic temperature) that is released from various containers for delivery to a patient (see Figures 1 and 2, col. 6, lines 1-2, 10-13, 50-51, 65-67 and col. 7, lines 19-20). At col. 3, lines 40-44, Heinonen elaborates that "the anesthetic concentration of a flow delivered to a patient during anesthesia is monitored and, as the concentration alters, the flow is adjusted in order to maintain the desired concentration within a set range." The Heinonen claims only serve to emphasize that only data regarding monitored anesthesia is provided to the ventilator (see claim 1, where sensor 29 is associated with a conduit for ascertaining the amount of anesthetic being supplied to the patient).

The mere fact that anesthesia flow to the patient can be automatically monitored and controlled in a feedback fashion does not suggest the further leap that patient height data can be input into the ventilator for use in setting the basic operating parameters of the ventilator. Thus, Heinonen neither teaches nor suggests how (or whether) to use the patient's body length in setting operating parameters of the ventilator. In fact, the emphasis on monitoring anesthesia delivery teaches away from the methods of the current invention that solely utilize patient body length.

The Haluszka reference merely discloses a method for assessing patient lung activity. In fact, Haluszka describes a surrogate to spirometry, a common method for respiratory

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had no reason to look to the Haluszka reference for guidance in developing a device or method wherein patient height alone can be used by a control system in the ventilator to provide appropriate ventilation to the patient. Accordingly, when the Haluszka reference is read in conjunction with the teachings of the Kanesaka and Heinonen references, the prior art, when read as a whole, teaches away from applying only a height-based measurement to a ventilator.

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Here, it is only the applicants' disclosure that provides a skilled artisan with the subject advantageous method for providing ventilation using data related to patient height. It is a basic premise of patent law that the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. In *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969), the CCPA specifically held that:

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is, we must view the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 122 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

Combining prior art references without evidence of a suggestion, teaching, or motivation simply takes the inventors' disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). Additionally, the Court of Customs and Patent Appeals has stated, "[i]n determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." In re Linter, 458 F.2d 1013, 1016 (CCPA 1972).

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicants' invention would not have made the modification or application

obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection. "[b]oth the suggestion and the expectation of success must be founded in the prior art...." *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed.Cir.1988).

The Kanesaka, Heinonen, and Haluszka *et al.* references all fail to teach or suggest any method for providing ventilation where the ventilator solely uses inputted patient body length to calculate appropriate ventilation operation parameters. Further, these references do not provide any motivation to modify their cited teachings without the guidance of the applicants' disclosure. Without such a motivation, no *prima facie* case of obviousness has been made. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection set forth under 35 U.S.C. §103.

In view of the foregoing remarks, the applicants believe that the currently pending claim is in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

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examination. The applicants respectfully submit that spirometry is a method typically used in the clinical assessment of lung condition, where a patient performs a series of respiratory maneuvers during which the patient's flow/volume is measured with a spirometer. The results of the spirometer tests reflect characteristics of lung volume and capacity. For example, spirometry yields a measure of a patient's vital capacity (VC), functional vital capacity (FVC)(also referred to a functional residual volume (FRV)), and FEV_1, which is the forced expiratory volume during one minute. These spirometry-measured volumes and capacities are well known and understood parameters that are used in the respiratory arts to measure the function of a patient's lung for disease diagnosis.

Haluszka merely reports that out of all of the physical features of the patient that were compared, the patient's height provides the best correlation with the spirometry measured volumes and capacities in children, which is useful in providing a basis for normal versus abnormal lung function. It can thus be appreciated that the Haluszka reference teaches a surrogate to spirometry, in which height measurement provides a basis for normal vital volumes and lung capacities for use in pediatric disease diagnosis. While such spirometry-measured vital capacities may be of interest in assessing lung function and for use in disease diagnosis, they are not used by a technician in setting up a ventilator.

Spirometry-measured volumes and capacities (such as VC, FVC, FEV_1), especially those predicted based on height via the Haluszka reference, do not serve to predict how a ventilator should be configured to deliver ventilation to a patient. For example, a ventilator typically must be set to deliver a certain tidal volume at a certain respiratory rate. Those skilled in the art understand that spirometry-measured volumes and capacities (VC, FVC, FEV_1) measured indirectly based on height (such as taught by the Haluska reference), do not correlate to a tidal volume or a respiratory rate. Further, those skilled in the art would not consider measuring the patient body length as an input to a ventilator because the volume or capacity measurement predicted based on height does not provide the correct volume, namely tidal volume V_T, needed to set up a ventilator.

Thus, the Haluszka reference does not motivate one skilled in the art to practice the presently claimed invention. There is no teaching that explains or even suggests that height alone can be used to a control system in the ventilator. Therefore, the skilled artisan would have